



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/580,295

05/23/2006

Holger Sellner

33529-US-PCT

4188

1095

7590

03/31/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/580,295 | Applicant(s) SELLNER ET AL. | |
| | Examiner MEGHAN FINN | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-17 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/23/07; 7/06/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I (claims 1-6, 9-17) and (S)-2-Amino-3-methyl-butyric acid (1S, 2S, 4S)-2 amino-1-[(S)-2-(2-carbamoyl-2-methyl-propylcarbamoyl)-3-methyl-butyl-4-[4-methoxy-3-(3-methoxy-propoxy)-benzyl]-5-methyl-hexyl ester, in the reply filed on January 07, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 07, 2009.

Claim Objections

Claim 11 is objected to because of the following informalities: on the second to last line of the claim applicant claims "in claim2" and there should be a space between "claim" and "2". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, and 9-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

Art Unit: 1614

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed compounds of formula I, and elected (S)-2-Amino-3-methyl-butyrlic acid (1S, 2S, 4S)-2 amino-1-[(S)-2-(2-carbamoyl-2-methyl-propylcarbamoyl)-3-methyl-butyl-4-[4-methoxy-3-(3-methoxy-propoxy)-benzyl]-5-methyl-hexyl ester as the elected species, referred hereafter as ES. Applicant has also claimed pharmaceutical compositions, including the ES in combination with a diuretic. Applicant has not shown how to make or use the compounds of the instant invention, including ES. For the elected species ES, and compounds of formula (IB), applicant has provided several example syntheses, however these do not start with a starting material that is known in the art or commercially available. Thus one of skill in the art at the time of the invention would not be able to make those compounds given the information provided without undue experimentation to first make the starting materials. Furthermore, for compounds beyond the formula IB (such as those of formula I and IA which are much broader), applicant has not provided examples of how to make these compounds that can vary very significantly in structure from those of formula IB.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2)

Art Unit: 1614

the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation necessary would be undue (1) because of the lack of direction provided towards synthesis of the starting materials and compounds that are structurally distinct from those of IB (2). The working examples are all directed towards compounds of the formula IB (3) and the examples directed towards use of the compound (inhibition of human renin) only says test compounds and never indicates what compounds were tested. The nature of the invention is the synthesis and use of complex organic compounds (4) of which the elected species ES is not known in the art (5) and while the relative skill of those in the art is high (6) the unpredictability of synthesizing a wide variety of compounds encompassed by the claims would also be high (7). The breadth of the claims is high due to the large number of compounds encompassed by formula I (8).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, applicant uses ambiguous language “preferably” and “may be present” in claim 5 uses “such as”, claims 12-13 also use “such as”. The use of such language is unclear as to whether that limitation is required or not. One of skill in the art would not be able to determine what the required limitations of those claims are, and thus claims 1-5 and 9-13 are rejected for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 rejected under 35 U.S.C. 102(b) as being anticipated by Dondoni et al. (Tetrahedron letters, 2001, vol. 41, pages 4819-4823, cited on applicant's IDS).

The elected species is free of the prior art, however Dondoni et al. anticipates several of the species claimed by applicant in claims 1 and 3. The compound Ia (page 4821, scheme 5) anticipates the genus of claims 1 and 3 where R1 and R4 are hydrogen, R2 and R3 are C1-C7-alkanoyloxy and/or C1-C7-alkoxy-C1-C7-alkoxy, X is methylene, R5 is C1-C7 alkyl, R6 is N-C1-C7-alkanoyl-amino, R9 is C1-C7 alkanoyl, R7 is C1-C7 alkyl, and R8 is hydrogen. Thus Dondoni et al. anticipates claims 1 and 3.

Conclusion

No claims are allowed. The elected species is free of the prior art.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

Application/Control Number: 10/580,295

Page 7

Art Unit: 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614